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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/673,643 10/31/00 YOKOI

M M&M-031-USA

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HM12/0815

EXAMINER

GRUN, J

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

08/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/673,643

Applicant(s)
YOKOI et al.

Examiner
James L. Grun, Ph.D.

Art Unit
1641



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-16 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 20) ☐ Other:

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 24 May 2001 is acknowledged and has been entered. Claims 7 and 8 have been cancelled. Claims 12-16 are newly added. Claims 1-6 and 9-16 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. When formal drawings are submitted, the draftsman will perform a review. Direct any inquiries concerning drawing review to the Drawing Review Branch at (703) 305-8404.

The specification is objected to and claims 1-2, 5-6, 9-11, and 13 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record that these claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Particularly, the invention commensurate with that as instantly claimed. As set forth, absent further description and guidance from Applicant, one would not be assured of the ability to practice the invention as claimed with an enzyme substrate which is also sterically inhibited from interacting with enzyme on the agglutinated solid phase. Signal modification would not be related

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to the action of the enzyme inhibitor in such a case. Moreover, for the reasons of record, one would not be assured of the ability to practice the invention with “plural different combinations in type of said antibody or antigen, enzyme and substrate” as instantly claimed if different antibody or antigen components were bound to the same carrier as disclosed.

Applicant's arguments filed 24 May 2001 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, the claims as now amended do not obviate the rejections of record.

Claims 2, 4, 11, and 16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2 it is not clear how the multiple reagents of the claim further limit “an immunoassay reagent” comprising components which are maintained separate and apart as claimed in the independent claim.

In claim 4 it is not clear how the multiple reagents of the claim further limit “an immunoassay reagent” comprising components which are maintained separate and apart as claimed in the independent claim.

In claim 11, the interrelationships of the components are not clear because “the absorbance” lacks antecedent basis and is vague as to what is being measured, e.g. it is not clear that the enzyme reaction contributes anything to the absorbance.

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In claim 16, the interrelationships of the components are not clear because it is not clear that the addition of components (b) and (c) contributes anything to the absorbance change or measurement.

Claims 1-6 and 12-13 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Kasahara et al (U.S. Pat. No. 4,582,792) for reasons of record in the prior rejection of the similar subject matter of claims 1-6.

Claims 1-6 and 12-13 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Kasahara et al (U.S. Pat. No. 4,649,105) for reasons of record in the prior rejection of the similar subject matter of claims 1-6.

Claims 1-6, 9-10, and 12-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over either of Kasahara et al (U.S. Pat. No. 4,582,792) or Kasahara et al (U.S. Pat. No. 4,649,105), in view of Ashihara et al (U.S. Pat. No. 4,621,048) for reasons of record in the prior rejection of the similar subject matter of claims 1-11.

Applicant's arguments filed 24 May 2001 have been fully considered but they are not deemed to be persuasive. Applicant's arguments drawn to the intended uses of the instantly claimed reagents, such as in agglutination reactions or in assays using absorbance measurements, as compared to the disclosed uses of the reagents of Kasahara et al were not found persuasive because the arguments were not germane to the instant questions of the novelty, obviousness, or patentability of the claimed reagents themselves. As set forth, the references of Kasahara et al,

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alone and/or as modified, teach the reagent components as instantly claimed. It is of no moment that the references conjugate the enzyme or enzyme inhibitor to a mobile ligand analog or to a mobile anti-ligand or to a mobile sandwiching antibody to form the combination material, as such is not excluded by the instant open claim language. Notwithstanding applicant's implication to the contrary, the reference did not contemplate the immobilization of both (ligand or anti-ligand) and (enzyme or enzyme inhibitor) only on different particles and only if the particles were larger than 3 mm diameter, but also contemplated the immobilization of both (ligand or anti-ligand) and (enzyme or enzyme inhibitor) on the same particle / polymer, irregardless of size.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

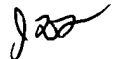
A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The Examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399. The fax phone numbers for official communications to Group 1640 are (703) 305-3014 or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



James L. Grun, Ph.D.
August 14, 2001



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641